OCT 2 2 2010

K102135

510(k) SUMMARY

VEGA System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Nuvon, Inc

One Rincon Center

101 Spear Street, Suite 255

San Francisco, CA 94105

Phone: 1-215-966-6142

Facsimile: 1-267-499-2001

Contact Person: John R. Zaleski

Date Prepared: July 20th, 2010

Name of Device and Name/Address of Sponsor

VEGA System

Nuvon, Inc.

One Rincon Center

101 Spear Street, Suite 255

San Francisco, CA 94105

Common or Usual Name

Physiological and biomedical device data retrieval system and standard industry format (e.g.: XML, HL7) translator.

Classification Name/Product Code/CFR Reference

Software, transmission and storage, patient data

Product Code: NSX, MWI

CRF Reference: Not classified

Predicate Device

Data Captor, K032142, developed by Capsule Technologie, Inc.

Intended Use / Indications for Use

The VEGA System is intended to be used for data collection from bedside and point of care biomedical devices and clinical information management systems either directly or through networks with independent bedside devices. The Vector Event Grid Architecture System is not intended for monitoring purposes, nor is it intended to control any of the biomedical devices and information systems with which it interconnects."

Technological Characteristics

The VEGA System permits the transfer of data from biomedical and patient care devices to existing hospital information technology and electronic medical record systems. The VEGA System connects directly to biomedical devices and aggregates the data from multiple biomedical

devices for transmission to electronic medical record systems. The VEGA System may also translate native biomedical device data into the HL7 standard as necessary.

Performance Data

Results of verification and validation activities have shown that the VEGA System biomedical device data are communicated from the source devices through the system in a manner consistent with the expected performance. In all instances the VEGA System functioned as intended and the fidelity of the results observed was as expected.

Substantial Equivalence

The VEGA System is substantially equivalent to the Capsule Technologie Data Captor product. The VEGA System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the VEGA System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the VEGA System has substantially equivalent performance to the Data Captor System. Thus, the VEGA System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nuvon, Inc.
c/o Mr. Jonathan S. Kahan
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

OCT 2 2 2010

Re: K102135
Trade/Device Name: Vector Event Grid Architecture (VEGA) System
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LNX
Dated: March 12, 2010
Received: March 15, 2010

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102135

OCT 2 2 2010

Device Name: Vectored Event Grid Architecture (VEGA) System

Indications for Use:

The Vector Event Grid Architecture System is intended for use in data collection from bedside and point of care biomedical devices and clinical information management systems either directly or through networks with independent bedside devices. The Vector Event Grid Architecture System is not intended for monitoring purposes, nor is it intended to control any of the biomedical devices and information systems with which it interconnects.

Prescription Use X AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102135

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